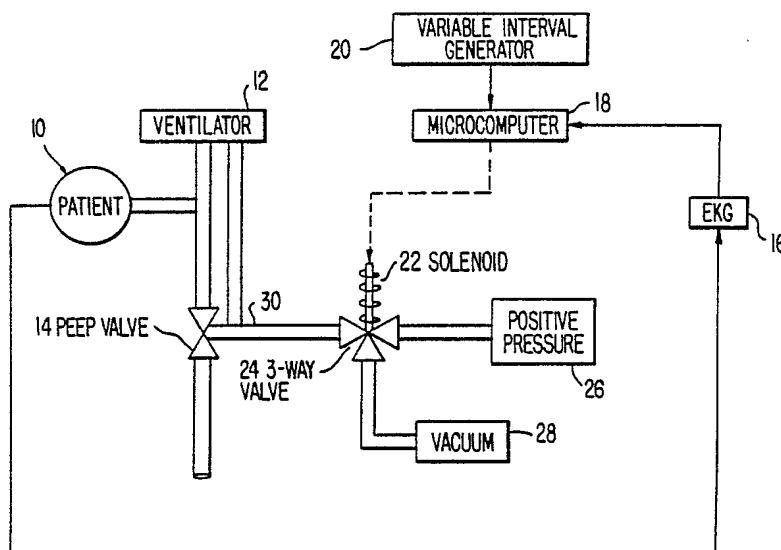




INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(21) International Application Number: PCT/US87/00644 (22) International Filing Date: 27 March 1987 (27.03.87) (31) Priority Application Number: 845,942 (32) Priority Date: 31 March 1986 (31.03.86) (33) Priority Country: US (71) Applicant: PURITAN-BENNETT CORPORATION [US/US]; 9401 Indian Creek Parkway, Overland Park, KS 66225-5905 (US). (72) Inventors: CUMMINGS, Charles, C. ; 291 West Green- wood Avenue, Lansdowne, PA 19050 (US). PRINCE, Robert, I. ; 4912 S.W. 83rd Terrace, Gainesville, FL 32067 (US).		(74) Agent: FINCH, Walter, G.; 1501-03, Fidelity Bldg., Baltimore, MD 21201 (US). (81) Designated States: AT, AT (European patent), AU, BB, BE (European patent), BG, BR, CH, CH (European patent), DE, DE (European patent), DK, FI, FR (Eu- ropean patent), GB, GB (European patent), HU, IT (European patent), JP, KP, KR, LK, LU, LU (Euro- pean patent), MC, MG, MW, NL, NL (European pa- tent), NO, RO, SD, SE, SE (European patent), SU. Published <i>With international search report.</i>

(54) Title: COMPUTER GATED POSITIVE EXPIRATORY PRESSURE SYSTEM**(57) Abstract**

The use of Positive-End-Expiratory Pressure (PEEP) systems result in decreased cardiac output and decreased regional blood flow because the heart is surrounded by higher than usual pressure (elevated intrathoracic pressure). The invention lowers intrathoracic pressure selectively during a small portion of the heart cycle when it causes its greatest detriment. The invention lowers thoracic pressure by providing a low pressure source to the PEEP valve (14). Included in the invention are a sensing means (16) for sensing sequential heart beats of a patient, together with a computing means (18), which is connected to the sensing means (16), for computing a period between the sequential heart beats. In addition, a valve means (24) is connected electrically to the computing means (18) and pneumatically to ventilator means (12) for controlling the ventilator means (12), with the valve means (24) being positioned to cease supply of positive pressure in response to the computed period.

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TITLE OF THE INVENTION

Computer Gated Positive Expiratory Pressure System

BACKGROUND

When breathing normally, one's diaphragm is dropped to increase one's thoracic cavity, thus creating a negative pressure in the thoracic cavity, relative to atmospheric pressure. Air is driven by the atmospheric pressure into the negative-pressure thoracic cavity. Many patients, such as victims of accidents suffering from shock, trauma or heart attack, may require a respirator or ventilator to aid breathing. Prior respirators used intermittent, positive pressure breaths to increase the pressure within a patient's lungs until filled. Air is expelled passively by the natural stiffness of the lungs.

Such respirators drive a positive pressure breath into the lungs which are already at atmospheric pressure. The pressure in the lungs is increased above atmospheric pressure, contrary to normal occurrence, which inhibits the heart's ability to pump blood. During normally respiration, negative thoracic pressure is developed upon inspiration of air, which aids in filling the heart with blood. The resultant pressure gradient (the relatively positive pressure in the periphery and

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negative pressure in the thorax) helps to fill the heart as it opens, subsequent to the heart's squeezing or pumping motion. If however, the pressure in the thoracic chamber is increased, as with respirators, the amount of blood returning or entering the heart is decreased. The heart also must squeeze against a higher pressure. A lower cardiac output results.

The common technique for improving arterial oxygen tension is the use of Positive-End-Expiratory Pressure (PEEP), where a low level of positive pressure is maintained in the airway between positive pressure breaths. PEEP uses a standard switch. A pressure signal applied to the valve controls the high or low pressure states of the valve. The low PEEP state is generated when the valve is fully open. A partial closing of the valve creates high intrathoracic pressure between breaths, as some air from the tidal volume is not allowed to escape. However, at 10 centimeters of water pressure of PEEP, cardiac output drops significantly. Intravenous fluids are used to increase intravascular volume in an effort to minimize this fall in cardiac output. The patient may already have compromised cardiac function, minimizing or negating the advantages of the intravascular volume increase. Additionally, patients

requiring respirators typically lack adequate kidney function and cannot process the added fluids. If too much intravenous fluid is used, relative to the patient's ability (aided or not) to process the fluid, the fluid may enter the patient's lungs.

Positive inotropic agents are used to increase the squeeze of the heart to pump more blood. Obviously, the heart works harder than normal resulting in possible heart attacks or arrhythmias. Often, physicians will prescribe a combination of increased intravenous fluids and positive inotropic agents with PEEP.

Several investigators have evaluated the effect of cardiac cycle-specified, increases in thoracic pressure on cardiac output. They synchronized high frequency jet ventilation to various phases of the R-R interval. Carlson and Pinsky found that the cardiac depressant effect of positive pressure ventilation is minimized if the positive pressure pulsations are synchronized with diastole. Otto and Tyson, however, found no significant changes in cardiac output while synchronizing positive pressure pulsations to various portions of the cardiac cycle.

Pinchak described the best frequency in high frequency jet ventilation. He also noticed rhythmic

oscillations in pulmonary artery pressure (PAP) and also rhythmic changes in systemic blood pressure. A possible explanation for these oscillations is that the jet pulsations move in and out of synchrony with the heart rate. In evaluating his data it appears that when jet airway pressure peak occurred during early systole there was a high pulmonary artery pressure, and a low systemic blood pressure. While Pinchak does not comment on this, his recorded data show that pulmonary artery pressure was waxing and waning precisely opposite to the blood pressure. A plausible explanation is an increase in pulmonary artery pressure is simply a reflection of an increase in pulmonary vascular resistance which causes a decrement in left ventricular filling and thus decrease in systemic blood pressure secondary to a decrease in cardiac output. If the slight oscillations in the systemic blood pressure reflect oscillations in cardiac output, then Pinchak's study would support Pinsky and Carlson's work, suggesting that positive airway pressure is least detrimental during diastole.

SUMMARY OF THE INVENTION

The invention concerns a computer-gated,

positive expiratory pressure system for supplementing positive end-expiratory pressure (PEEP) systems. The output of a cardiogram machine is amplified and squared, or an LED of a cardiogram machine is optically monitored, to determine an R-wave, or the beginning of electrical systole. A signal is fed to a multiplier where the R-R wave signal (period) is multiplied representing the duration of the R-R wave with a variable interval set by a physician. The resultant produce (R-R wave times variable interval) is used to trigger a solenoid operated 3-way valve. The 3-way valve is normally closed to pass a positive pressure to a standard PEEP valve which functions normally. When triggered, the 3-way valve opens to allow a relatively low pressure to pass to the PEEP valve such that the PEEP valve creates a low pressure to the patient.

Thus, PEEP is removed for a variable time ratio immediately before a next heart beat. The PEEP valve is controlled by computer gating a 3-way valve to create pressure drops, allowing the heart to fill. Once the heart fills, PEEP is resumed without any detrimental effects. Respiration of the patient is coordinated with the patient's heart beat to maximize cardiac output. Additionally pressure can be replaced

immediately after drop out in an effort to improve emptying of the heart.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a schematic of the present invention in its environment.

Figure 2 is a block diagram of the Figure 1 microcomputer contents, as connected to a 3-way valve.

Figure 3 reveals a second embodiment for detecting a heart beat interval.

DETAILED DESCRIPTION OF THE INVENTION

The computer-gated, positive expiratory pressure system is shown in Figure 1 in its environment, connected to a therapeutic device such as a PEEP system. A patient 10 is shown using a respirator or ventilator 12 via a standard expiratory (PEEP) valve 14. The PEEP valve 14 opens and closes to allow low and high pressures to the patient 10. In accordance with the present invention, the patient 10 is also connected to a cardiogram machine (EKG) 16. Successive heart beats are detected by the EKG 16 and a signal representing each beat is output to a microcomputer 18, the details of which are discussed regarding Figures 2 and 3. A variable interval is generated by generator 20 as a

second input to the microcomputer 18, the value of the interval being set by the attending physician. The microcomputer 18 combines the variable interval signal from 20 and a value representing the period between successive heart beats from EKG 16 and generates a controlling output to a solenoid 22 of a 3-way valve 24. The 3-way valve 24 is connected by a first end to a positive pressure source 26. A second valve end is pneumatically connected to a low relative pressure 28, while a third end is connected to the PEEP valve 14 via which the patient 10 received the positive pressure breaths.

Under normal operation of the ventilator 12, the PEEP valve 14 is operated to allow alternate low and high positive pressure breaths (approximately .4 psi) from the ventilator 12 to pass directly to the patient 10. However, in response to the output of microcomputer 18, the solenoid 22 is energized to yield at output 30, a negative pressure from the low relative pressure source 28. The negative pressure output at 30 opens the PEEP valve 14. Because the PEEP valve 14 is fully opened, a low pressure is received by the patient 10 from the ventilator 12. The resultant low pressure, in accordance with the present invention, occurs just

prior to a predicted heart beat to insure the heart, when filling, does not work against high pressures. PEEP systems per se too often generate high pressures when the heart beats, inhibiting heart filling and decreasing cardiac output.

In Figure 2, the details of microcomputer 18 are evident. The output of EKG 16 is run through an operational amplifier 32 to a timer 34 which squares the amplified EKG signal to develop a series of electrical pulses corresponding to successive heart beats. The electrical pulses of timer 34 are received by memory/calculator 36 which determines a period representing the interval between successive heart beats. This period is used to predict a next heart beat so a low pressure is delivered to the patient slightly before and during this next heart beat. The variable interval generator 20 is set by the attending physician between 15 and 400 microseconds, for instance, by typical analog controls. The variable interval signal from 20 and the period signal from calculator 36 are used to generate a product in multiplier 38. The resultant product is used as a signal to energize the solenoid 32, to control 3-way valve 24.

In a normal state, 3-way valve 24 connects the positive pressure 26 to the output 30, putting PEEP valve 14 in a partially closed position. Thus, the ventilator 12 can generate a high, positive pressure breath to the patient 10. However, assume the EKG 16 detects a heart beat each second. The EKG signal is amplified at 32, squared by timer 34, and the period of one second calculated in memory 36. If the variable interval generator is set by the physician for 0.8 second, multiplier 38 forms a product of the period and variable interval. (1.0×0.8) equal to 0.8 seconds. Thus, 0.2 second before the next predicted, heart beat (0.8 second from the last heart beat) solenoid 22 is energized. The 3-way valve 24 now opens output 30 to the vacuum 28. Accordingly, a resultant negative pressure fully opens the PEEP valve 14 and a low pressure reaches the patient. Should the heart rate vary, the difference between predicted and actual heart beats will be detected and pulse timing corrected. The time duration of the pulse to the solenoid is controlled by a second timer (not shown).

Figure 3 reveals a second embodiment for determining or sensing heart beats. A photodetector 40 is used to detect the blinking LED 42 which is typically part of a cardiogram machine. The

photodetector 40, turning on and off with the flash of the LED 42, requires no timer or wave squarer, and thus is input directly to the amplifier 32 for subsequent processing in the manner of the Figure 2 embodiment.

Other modifications are apparent to those skilled in the art which do not depart from the spirit of the present invention, the scope being defined by the appended claims. For instance, rather than use a microcomputer, a microprocessor (e.g. C 64 Commadore Computer) may be adapted and software developed to monitor and determine beat period, with a programmable variable interval for use by the physician.

What is claimed is:

1. A gating system for controlling a ventilator means which generates a positive pressure breath, the systems including:

a sensing means for sensing sequential heart beats of a patient;

a computing means, connected to the sensing means, for computing a period between the sequential heart beats;

a valve means connected electrically to the computing means and pneumatically to the ventilator means for controlling the ventilator means, the valve means positioned to cease positive pressure breaths in response to the computed period.

2. A system as in claim 1, including:

a vacuum means, pneumatically connected to the valve means, for generating a low pressure to the ventilating means via the valve means.

3. A system as in claim 2, including a positive pressure means, the valve means comprising a 3-way valve having first, second and third ends, the first end connected pneumatically to the ventilator means, the second end connected to the vacuum means,

and the third end connected to the positive pressure means.

4. A system as in claim 3, the 3-way valve having a solenoid electrically connected to the computing means, which positions the 3-way valve.

5. A system as in claim 4, including a variable means, connected to the computing means, for generating a variable interval signal to the computing means.

6. A system as in claim 5, the computing means having a multiplier means, connected to the sensing means and the variable means, for generating a product signal based on the computed period times the variable interval signal.

7. A system as in claim 6, the ventilator means having a gated valve pneumatically connected to the valve means first end, the gated valve opened by the valve means pneumatic connection of the relative low pressure source means to the ventilator means, and the gated valve closed by the valve means pneumatic connection of the positive pressure means to the ventilator means.

8. A pneumatic control system for a patient's therapeutic device including:

a pneumatic valve through which a fluid may flow;

a sensing means for sensing a patient's sequential heart beats and generating beat signals;

a computing means, connected to receive the sensed beat signals, for computing a period between sequential beat signals, and for generating a period signal;

a variable means for generating a variable interval signal;

a combining means, connected to receive and combine the period signal and the variable interval signal, and connected to the valve means, for controlling the valve means in response to the combined period signal and variable interval signal.

9. A system as in claim 8 including a low pressure source means, pneumatically connected to the valve means, for creating a relative negative pressure when the valve means is opened.

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10. A system as in claim 9, including a positive pressure means, the valve means comprising a 3-way valve having three end means;

a first end means for connection to the therapeutic device, a second end means for connection to the vacuum means, and a third end means for connection to the positive pressure means.

11. A system as in claim 10, the 3-way valve having a solenoid electrically connected to the computing means, which positions the 3-way valve.

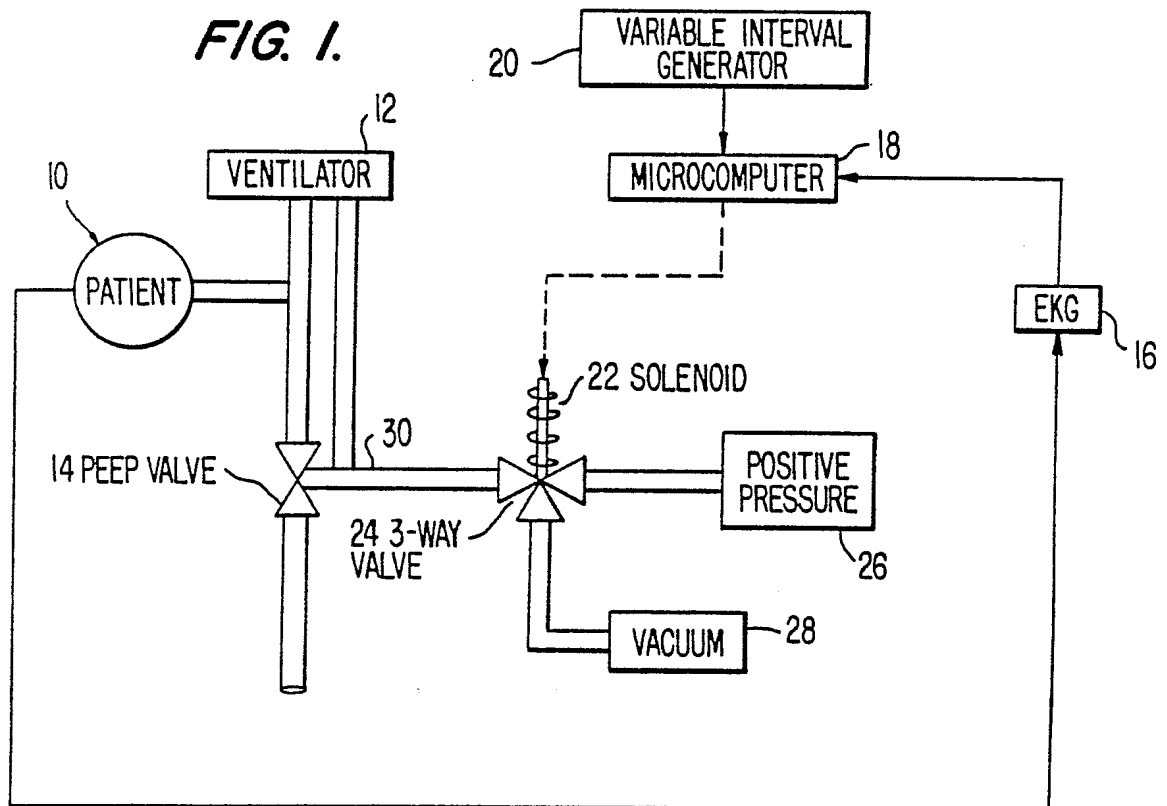
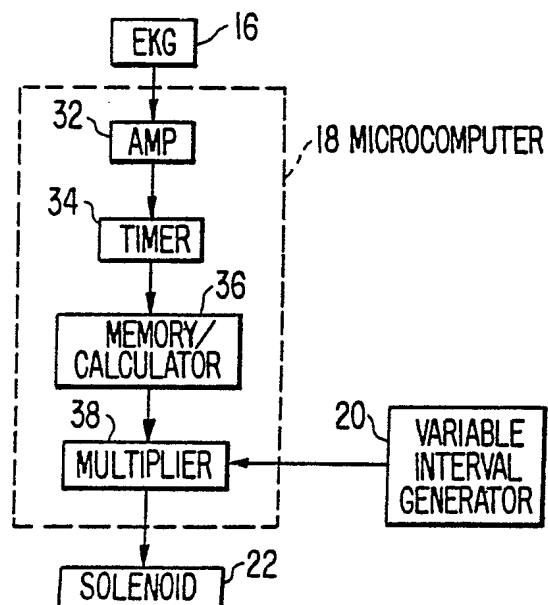
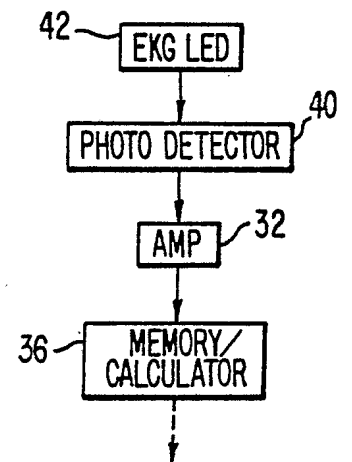
12. A system as in claim 11, the computing means comprising a multiplying means, connected to the sensing means and the variable means, for generating a product signal based on the computed period times the variable interval signal.

13. A system as in claim 12, the sensing means having an amplifying means connected to the sensing means, for amplifying the beat signal.

14. A system as in claim 13, the computing means including a timing means, connected to the amplifying means, for squaring the beat signal, and for generating pulses to the multiplying means.

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15. A system as in claim 12, the sensing means including a photodetector means for detecting light signals in response to a patient's heart beat, the photodetector means generating an output to the amplifying means.

FIG. 1.**FIG. 2.****FIG. 3.**

INTERNATIONAL SEARCH REPORT

International Application No **PCT/US87/00644**

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) ³		
According to International Patent Classification (IPC) or to both National Classification and IPC		
IPC(4): G06F 15/42 US 364/417; 128/204.23		
II. FIELDS SEARCHED		
Minimum Documentation Searched ⁴		
Classification System	Classification Symbols	
US	364/417; 137/908; 251/30 128/204.21, 204.23, 204.18, 205.24, 205.25	
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched ⁵		
III. DOCUMENTS CONSIDERED TO BE RELEVANT ¹⁴		
Category [*]	Citation of Document, ¹⁶ with indication, where appropriate, of the relevant passages ¹⁷	Relevant to Claim No. ¹⁸
A ₁ P	US, A, 4,617,924 (HEIM) 21 October 1986, see Figure 2.	1, 8
A	US, A, 4,182,366 (BOEHRINGER) 8 January 1980, see entire document.	1, 8
A ₁ P	US, A, 4,613,111 (PAQUET) 23 September 1986, see column 1 line 41-column 2 line 17.	3
A	US, A, 4,211,221 (SCHWANBOM) 8 July 1980, see entire document.	1, 8
A	US, A, 4,318,399 (BERNDTSSON) 9 March 1982, see column 2 lines 18-51.	1, 8
<div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p>[*] Special categories of cited documents: ¹⁵</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> </div> <div style="width: 45%;"> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"&" document member of the same patent family</p> </div> </div>		
IV. CERTIFICATION		
Date of the Actual Completion of the International Search ²	Date of Mailing of this International Search Report ²	
26 May 1987	11 JUN 1987	
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ISA/US	Gail Hayes <i>Gail Hayes</i>	